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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/660,742   | 09/12/2003  | Ratan K. Chaudhuri   | EMI-61                       | 4932             |
| 23599 7590 12/27/2006<br>MILLEN, WHITE, ZELANO & BRANIGAN, P.C.<br>2200 CLARENDON BLVD.<br>SUITE 1400<br>ARLINGTON, VA 22201 |             |                      | EXAMINER<br>FLOOD, MICHELE C |                  |
|  |             |                      | ART UNIT                     | PAPER NUMBER     |
|  |             |                      | 1655                         |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE            | DELIVERY MODE                |                  |
| 3 MONTHS   |             | 12/27/2006           | PAPER                        |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/660,742

Applicant(s)

CHAUDHURI ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,7,8,13,14,16-18,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,7,8,13,14,16-18,40 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on October 13, 2006 with the cancellation of Claims 1-4, 9-12, 15 and 19-39, and the addition of newly submitted Claims 40 and 41.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 5, 7, 8, 13, 14, 16-18, 40 and 41 are under examination.**

### ***Response to Arguments***

Claims 13, 14, 16, 17, 18, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bound of Claim 13, as drafted in its entirety, are rendered uncertain because it is unclear as to the subject matter Applicant intends to direct the instantly claimed invention since the process according to Claim 5 results in the making of "an enriched aqueous extract of *Emblica officinalis* dissolved components", whereas the process according to Claim 13 results in the making of "an enriched extract of *Emblica officinalis* macroscopically substantially to completely devoid of black specks". As drafted, it is unclear as to whether the process according to Claim 7 results in the making of the same product prepared by the process of Claim 5. The lack of clarity renders the instantly claimed invention vague and ambiguous.

Claims 14 and 17 recite the limitation "the separated enriched aqueous extract of *Emblica officinalis*" in line 1 to line 2. There is a lack of clear antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

Claims 5, 7, as amended, and Claims 8, 13 and 14 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Ranjan et al. (U). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a process comprising enriching an extract of *Emblica officinalis* comprising the steps of: A) dispersing a powdered extract *Emblica officinalis* in an aqueous solution to form an aqueous suspension of *Emblica officinalis*, the aqueous suspension containing dissolved components of *Emblica officinalis* and water-insoluble components comprising black specks and/or oligomeric and polymeric tannins; and B) separating the water-insoluble components from the dissolved components to obtain an enriched aqueous extract of *Emblica officinalis* of dissolved components.

Applicant argues that the teachings of Ranjan fail to anticipate the instantly claimed invention because "there is no suggestion of dispersing a powdered extract so as to form an aqueous dispersion." Applicant further argues, "In Ranjan et al., the process describes the preparation of an extract by drying a sample of leaves, twigs or fruits in an oven, or grinding material, soaking in hot distilled water and thereafter boiling

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it and filtering it while hot. Thus, the step of filtering involves the production of an extract in the first instance, not a subsequent process of purifying the resultant powdered extract, which is the subject of Applicant's claims." Applicant's arguments have been fully considered but not found persuasive because Ranjan clearly teaches the instantly claimed invention. For example, Ranjan teaches a process comprising enriching an extract of *Emblica officinalis* comprising extracting finely ground (powdered) amla water to provide an aqueous suspension of *Emblica officinalis*, filtering the extract to obtain an extract; extracting the residue with water, which was similarly filtered; combining the filtrates, centrifuging the filtrates, and making the supernatant standard volume in water. Ranjan teaches that the prepared the extract contained soluble tannin, non-tannin and polyphenolic materials in the claim-designated amounts. See Table 1 on page 102, wherein Ranjan describes the amounts of the various dissolved components of the amla plant samples in terms of dry weight. Contrary to Applicant's interpretation of the teaching of Ranjan, the Office deems that the oven dried, finely ground plant material of *Emblica officinalis* as a powdered extract of the claim-designated plant. For instance, the definition of a powder is no more than "any solid substance reduced to a state of fine, loose particles by crushing, grinding, disintegration, etc."; and, the definition of a dispersion is no more than "a system of dispersed particles in a solid, liquid or gas". Applicant is invited to consult any dictionary or online dictionary to verify the meaning of the two terms. On page 161, under "Materials and Methods. 3. *Aqueous Extract*", Ranjan expressly teaches a process comprising enriching an extract of *Emblica officinalis* comprising dispersing a powdered

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extract of the claim-designated plant material to provide an aqueous suspension and separating the water-soluble components from the dissolved components to form an aqueous extract of *Emblica officinalis* dissolved components. Ranjan does not expressly teach that the aqueous solution of *Emblica officinalis* contains dissolved components of *Emblica officinalis* and water-insoluble components comprising black specks and/or oligomeric and polymeric tannins or that the process step of centrifugation obtains an enriched extract of *Emblica officinalis* macroscopically and substantially to completely devoid of black specks. However, the instantly claimed process is a two-step process for enriching an extract of *Emblica officinalis* comprising dispersing a powdered extract of the claim-designated plant ingredient in an aqueous solution to form an aqueous suspension containing dissolved components of *Emblica officinalis* and water-insoluble components comprising black specks and/or oligomeric and polymeric tannins; and separating the water-insoluble components from the dissolved components to obtain an enriched aqueous extract of dissolved components of *Emblica officinalis*; and, Ranjan does expressly teach soaking of the finely ground, oven-dried amla plant material in hot distilled water. Therefore, an aqueous suspension containing the claim designated ingredients are deemed inherent to the aqueous solution taught by Ranjan because the ingredients and the process steps of making the aqueous suspension are one and the same, as instantly disclosed by Applicant, since the method taught by Ranjan also encompasses a second process step of filtering the aqueous suspension of the powdered extract of *Emblica officinalis* and centrifuging the filtrate to obtain an aqueous extract of the claim designated powdered plant extract

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comprising soluble tannins, non-tannin and polyphenolic materials of the claim designated plant material. Given that the process taught by Ranjan comprises the same ingredients and the same process steps taught by Applicant as having the beneficial functional effect for obtaining an enriched aqueous extract of dissolved components of *Emblica officinalis*, the instantly claimed process, functional effects, experimental parameter for the separation of water-insoluble components comprising black specks and/or oligomeric and polymeric tannins from dissolved components, and resultant product of an enriched aqueous extract of dissolved components of *Emblica officinalis* are deemed inherent to the process taught by Ranjan, absent evidence to the contrary.

The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

Claims 5, 7, 8, 13, 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranjan et al. (U) in view of Ghosal (A2, US 6,124,2368) and Ghosal et al. (V). Newly applied as necessitated by amendment.

Applicant claims the process according to claim 14, wherein the drying step comprises spray drying of freeze drying. Applicant further claims the process according to claim 16, wherein the drying comprises freeze drying.

The teachings of Ranjan are set forth above. It is not clear from the teachings of Ranjan the method of drying the enriched aqueous extract of dissolved components of *Emblica officinalis* obtained in the prior art process. However, it would have been

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obvious to one ordinary skill in the art, and one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to dry the resultant aqueous extract of dissolved components of *Emblica officinalis* obtained in the process taught by Ranjan by either spray drying or freeze drying to provide the instantly claimed invention because at the time the invention was made spray drying and freeze drying of extracts of *Emblica officinalis* were routine and conventional in the art, as evidenced by the teachings of Ghosal (A\*) and Ghosal (V).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

**No claims are allowed.**

### ***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**MICHELE FLOOD**  
**PRIMARY EXAMINER**

Michele Flood  
Primary Examiner  
Art Unit 1655

MCF  
December 23, 2006